

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA

v.

MURTY VEPURI  
ASHVIN PANCHAL  
KVK-TECH, INC.

Case No. 21-132-HB

The Hon. Harvey Bartle III

**REPLY BRIEF OF DEFENDANT MURTY VEPURI IN SUPPORT OF HIS MOTION  
TO STRIKE PARAGRAPH 4 OF THE SUPERSEDING INDICTMENT AS  
IRRELEVANT AND PREJUDICIAL SURPLUSAGE UNDER  
FEDERAL RULE OF CRIMINAL PROCEDURE 7(D)**

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## INTRODUCTION

Paragraph 4 of the Superseding Indictment is both irrelevant and highly prejudicial. Its reference to a matter now three decades old (which was also resolved 15 years *before* the onset of the conspiracy charged in this case) serves only to tarnish Mr. Vepuri. Meanwhile, for the purported purposes for which the government seeks to reprise this ancient issue, the government has readily available evidence that is more probative and less prejudicial. In light of those alternatives, the government's insistence on the need to use this material is unpersuasive. This Court should grant Mr. Vepuri's motion to strike Paragraph 4.

### I. PARAGRAPH 4 IS IRRELEVANT TO THE OFFENSE CHARGED IN COUNT 1

The government insists that Paragraph 4 is relevant to demonstrate: (1) "Vepuri's experience with, and knowledge and understanding of, the FDA's regulations for generic drug manufacturing," Gov't Opp'n Br. at 45; and (2) "Vepuri's motive to conceal his true involvement in KVK's operations." *Id.* at 46. As explained below, these pretextual reasons are unfounded and unpersuasive.

#### A. Even If The Able Labs Consent Order Is Probative Of Mr. Vepuri's *General* Awareness Of The Existence Of FDA Regulations, Such General Awareness Is Irrelevant To His *Specific* Knowledge Of The FDA Regulations At Issue Here

Paragraph 4 has become relevant, in the government's view, because Mr. Vepuri joined in Defendant KVK-Tech Inc.'s motion to dismiss, which argued that there was no requirement for KVK to notify the FDA of the change in UCB's manufacturing site and that even if there was, the requirement was unclear by the FDA's own admission. *See* Dkt. No. 96 at 13-16. Having joined in that argument, the government claims, Mr. Vepuri has made relevant his knowledge of the purported regulatory requirement at issue in this case. *See* Gov't Opp'n Br. at 46 (suggesting Mr. Vepuri's joinder has "signaled that a core tenet of his defense will be that he did not understand

the FDA regulations”). However, it does not follow that Mr. Vepuri’s knowledge of other regulatory issues not at play here are relevant to his knowledge of the specific regulatory requirement in this case.

The regulations at issue in this case are specific to whether and which post-approval supplement was allegedly required to be filed due to a change in manufacturing. These regulations are highly technical, and even by the FDA’s own admission, unclear. *See* Dkt. No. 96 at 13-16. The Able Labs matter referenced in Paragraph 4 did not involve any allegations related to the failure to file a post-approval supplement. Paragraph 4 establishes, at best, Mr. Vepuri’s *general* awareness of the existence of a regulatory regime that is wholly irrelevant to his defense relating to his lack of *specific* understanding of the requirements of technical regulations regarding post-approval supplements at issue here. This difference is significant, as the government will have to prove Mr. Vepuri’s agreement with another to violate the substantive offenses in Count 1 and the regulatory requirements flowing from them, and that he had the specific intent to defraud the FDA in this way. *See, e.g., United States v. Hartline*, 2016 WL 8716246, at \*5 (E.D. Pa. Sept. 16, 2016) (“The Court recognizes that in order for the Government to prove conspiracy under 18 U.S.C. § 371, it is ‘required to prove at least the degree of criminal intent necessary for the underlying substantive offense.’” (citing *United States v. Brodie*, 406 F.3d 123, 147 (3d Cir. 2005)), *aff’d*, 746 F. App’x 124 (3d Cir. 2018); *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 443 n.20 (1978) (“In a conspiracy, two different types of intent are generally required—the basic intent to agree, which is necessary to establish the existence of the conspiracy, and the more traditional intent to effectuate the object of the conspiracy.”); *Brodie*, 403 F. 3d at 147 (explaining that for a § 371 charge, the government was required to prove specific intent to violate the underlying statutes); *United States v. Willhite*, 98 F. App’x. 350, 352 (5th Cir. 2004) (“The Government’s evidence was

sufficient to make out a violation of 21 U.S.C. § 333(a)(2) because it demonstrated that [the defendant] intentionally violated § 331(a) with the specific intent to defraud or mislead the FDA.”).

Paragraph 4’s discussion of the Able Labs order is plainly unnecessary to satisfy the elements of the charged offense, and is therefore irrelevant to Count 1. *See United States v. Cooper*, 384 F. Supp. 2d 958, 960 (W.D. Va. 2005) (citing the Fourth Circuit’s relevance standard that “the question is whether that material is ‘unnecessary’ in making out a *prima facie* pleading of the violation”). But the government argues that this view of relevance in the context of a motion to strike surplusage is unduly narrow, and that the relevance standard in the Third Circuit is broader. *See Gov’t Opp’n Br.* at 48 n.27. In support of this argument the government cites two trial court opinions, but no decision of the Third Circuit. Indeed, our research likewise has not revealed any clear departure by the Third Circuit from the position of the Fourth Circuit, as reflected in *Cooper*. The opposing statements by two trial courts within the Third Circuit are, of course, not controlling and also do not signal the future path of the Third Circuit. On the contrary, it would make more sense for the Third Circuit to follow the reasoned approach of the Fourth Circuit, which fits better the logic of Rule 7, as well as the common understanding that an indictment is not evidence. *See Third Circuit Model Crim. Jury Instr.* § 3.02 Evidence (“The following are not evidence . . . [t]he indictment.”).<sup>1</sup> It makes sense that the standard of relevance

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<sup>1</sup> The government’s reliance on *Jimenez* is unavailing. *See Gov’t Opp’n Br.* at 47 (citing *United States v. Jimenez*, 824 F. Supp. 351 (S.D.N.Y. 1993)). First, the challenged language in *Jimenez* is distinguishable from the language here because Paragraph 4 does not contain language that is part of the charged conspiracy at all. The *Jimenez* court concluded the challenged “manner and means” section was “drafted in neutral and non-inflammatory language.” *Id.* Here, the mere inclusion of Paragraph 4 is highly prejudicial, as argued below.

applied to a pleading under Rule 7 should be narrower than the broader standard of relevance for the admissibility of evidence.<sup>2</sup>

Furthermore, trial courts' opinions within the Third Circuit are apparently not uniform. In *United States v. Georgiou*, 2009 WL 4641719, at \*6 (E.D. Pa. Dec. 7, 2009), for example, the indictment described losses suffered by a company, Caledonia, from the defendant's alleged conspiracy and stated: "Because Caledonia was unable to cover those massive losses, the firm could no longer operate and was liquidated." The defendant successfully moved to strike that statement as surplusage. The Court held that even though evidence showing loss was relevant to show the defendant's specific intent to defraud, the additional statement about liquidation was properly excluded under Federal Rule of Evidence 403 because its probative value was substantially outweighed by the danger of unfair prejudice. *Id.* at \*7. The court concluded that the fact that Caledonia was dissolved as a result of its losses ***went beyond what was necessary to prove the defendant's specific intent to defraud.*** *Id.*

*Cooper* is directly on point, and the government's attempt to distinguish it is unpersuasive. The government notes that the *Cooper* Court struck twenty paragraphs from the indictment (described as a "preamble"), while Mr. Vepuri seeks to strike just Paragraph 4. *See* Gov't Opp'n Br. at 47-48. If anything, this suggests that Mr. Vepuri's proposed excision would have even less impact on the government's charging document. Furthermore, the volume of surplusage in *Cooper* was not the basis for the court's granting of the motion to strike. *See Cooper*, 384 F. Supp. 2d at 960-61. Indeed, even a little surplusage is too much surplusage. *See, e.g., United States v. Salerno*, 2011 WL 6141017, at \*7 (M.D. Pa. Dec. 9, 2011) (granting motion to strike surplusage contained

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<sup>2</sup> Of course, even if this Court declines to strike Paragraph 4, the allegations of that paragraph would be inadmissible under Federal Rules of Evidence 404(b) and 403.

in two paragraphs in the indictment); *United States v. Alsugair*, 256 F. Supp. 2d 306, 317 (D.N.J. 2003) (granting motion to strike just the two words “and others” from the indictment, as surplusage). After all, “[s]urplusage’ is any fact or circumstance set forth in the indictment which is not a necessary ingredient of the offense.” *United States v. Manginen*, 565 F. Supp. 1024, 1025 (E.D. Va. 1983) (citation omitted), *aff’d*, 788 F.2d 1561 (4th Cir. 1986).

The general knowledge suggested obliquely by Paragraph 4 could lead, at most, to only the blandest of uncontroverted conclusions: that Mr. Vepuri *generally* “was knowledgeable about regulatory requirements placed on drug manufacturers, including that drug manufacturers shall identify, prevent, and correct deficiencies that can impact drug safety and efficacy.” Superseding Indictment ¶ 4. That is not probative at all of Mr. Vepuri’s specific knowledge and intent in this case, which is the only knowledge relevant to Count 1.

**B. Mr. Vepuri Had No Motive To Conceal His Role At KVK Because The FDA Order Did Not Impose A Lifetime Bar On Mr. Vepuri’s Ability To Earn A Livelihood In The Pharmaceutical Industry**

The government also claims that Paragraph 4 is relevant to show Mr. Vepuri’s motive to conceal his role at KVK from the FDA, purportedly because, decades ago, he promised the FDA, under the terms of a consent decree, that he would never again be a “responsible official” at any pharmaceutical company. *See* Gov’t Opp’n Br. at 2, 46-47. This claim is self-evidently untrue, as the documents in that litigation (which the government possesses) reveal.

In 1992, Mr. Vepuri entered a consent decree requiring certain compliance measures that would sunset in two years if he gave up control over work at Able Laboratories or any affiliated drug makers. *See* Exhibit A, Agreed Order of Permanent Injunction, *United States v. Able Labs., Inc.*, No. 91 Civ. 4916 (D.N.J. April 8, 1992). But in reaching that agreement, he was not signing away his ability to earn a living in his chosen profession, and a fair reading of the subsequent 1993 “FDA restraining order” referred to in Paragraph 4 of the Superseding Indictment (the “Order”)

does not suggest otherwise. *See* Exhibit B, Stipulated Order Amending Agreed Order of Permanent Injunction at 3-4, *United States v. Able Labs., Inc.*, No. 91 Civ. 4916 (D.N.J. May 24, 1993). Indeed, Paragraph 4’s reference to the Order is based upon a clear misreading of the plain language and import of the Order, and the government’s apparent unawareness of Mr. Vepuri’s release from the Order long before the alleged conduct in this case. Thus, the government’s suggestion that Mr. Vepuri was motivated to conceal a role he was not barred from having makes no sense, proving again that Paragraph 4 is relevant only to smear Mr. Vepuri.

*First*, the government mischaracterizes the Order by intimating that it implies a lifetime bar on Mr. Vepuri’s work in the pharmaceutical industry that it clearly never imposed.<sup>3</sup> Specifically, the government reads the Order excessively broadly to mean that “Vepuri agreed to refrain from exercising any authority over operations at Able and that he would not be an officer, director, employee or otherwise responsible official of *any business entity* engaged in the manufacture, processing, packing, or holding of drugs.” Gov’t Opp’n Br. at 2 (emphasis added). But the Order did not, contrary to the government’s allegation, limit Mr. Vepuri’s involvement in *other* drug manufacturing companies *with no affiliation to Able Labs*, such as KVK. It simply precluded Mr. Vepuri from exercising final authority over: (1) “manufacturing or quality assurance/quality control procedures or personnel *at Able* or any other drug manufacturing firm *affiliated with A.L. Laboratories* at which he may be employed”; (2) “any work *at Able* or any other drug manufacturing firm *affiliated with A.L. Laboratories* in support of a New Drug Application or Abbreviated New Drug Application”; (3) “any validation or manufacturing and

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<sup>3</sup> This Court may take judicial notice of the filings in *United States v. Able Labs.*, No. 91-4916 (D.N.J. Nov. 6, 1991) because they are matters of public record. *See Smith v. Lynn*, 809 F. App’x 115, 117 (3d Cir. 2020) (“[I]n deciding a motion to dismiss, a district court is permitted to review matters of public record and take judicial notice of a prior judicial opinion.”).

laboratory processes *at Able* or any other drug manufacturing firm *affiliated with A.L. Laboratories*"; and (4) "any business-required contact between research and development and manufacturing and quality control/quality assurance departments *at Able* or any other drug manufacturing firm *affiliated with A.L. Laboratories* at which he may be employed." Exhibit B (emphasis added). Neither Mr. Vepuri, nor any reasonable reader of the Order could have interpreted its limited application to suggest a lifetime bar from continuing to earn a livelihood in the pharmaceutical industry, which the Order plainly did not do.

*Second*, after the two-year period, Mr. Vepuri sought relief from the consent decree, attesting that he was not, and, "as of the date of the order releasing [him] from further obligations under the" consent decree, would "not be, an officer, director, employee or an otherwise responsible official of any business entity engaged in the manufacture, processing, packaging, or holding of drugs." Exhibit C, July 10, 1995 Aff. of Murty Vepuri in Support of Petition for Relief from Agreed Order of Permanent Injunction at ¶ 4, *United States v. Able Labs.*, No. 91 Civ. 4916 (D.N.J. August 3, 1995). Plainly, Mr. Vepuri was making a representation about his status "as of the date" of the requested order to show that he satisfied the conditions for relief; he was not promising to never again work as a responsible official in the pharmaceutical industry (a remedy the government had not even sought in the underlying case). And he obviously was not promising to assume an even more stringent bar than the limited two-year bar the parties had previously agreed to in connection with pharmaceutical work at Able Labs or its affiliates.

Mr. Vepuri was *released* from the Order on August 4, 1995—nearly *a decade* before KVK's formation and a *decade-and-a-half* before the start of the charged conspiracy period. *See* Exhibit D, Order Releasing Defendants From Further Obligations Under the Agreed Order of Permanent Injunction at 1, *United States v. Able Labs.*, No. 91-4916 (D.N.J. August 4, 1995)

(ordering that “Murty Vepuri is hereby released from further obligations under the Agreed Order [of Permanent Injunction of April 8, 1992, as amended May 24, 1993], and the Agreed Order is terminated as to Mr. Vepuri”). The period of the alleged conspiracy is from “in or about October 2010 through at least in or about March 2015,” with the conspiracy allegedly bookended by overt acts or omissions occurring on October 29, 2010 and March 2, 2015. *See* Superseding Indictment at 6 ¶ 16; 7 ¶ 1; 14 ¶ 19. Mr. Vepuri clearly had no motive to conceal his role or relationship to KVK under the long-expired Order as of the onset of the alleged conspiracy in 2010.

## **II. THE GOVERNMENT CONCEDES PARAGRAPH 4’S PREJUDICE TO MR. VEPURI**

Notably, the government concedes Paragraph 4’s prejudice. *See* Gov’t Opp’n Br. at 48 (arguing against striking Paragraph 4 “even if it might put Vepuri in a negative light”). Ironically, the government’s protestations as to how little (in the government’s eyes) Paragraph 4 prejudices Mr. Vepuri actually demonstrate how unimportant the paragraph is to the government. From the government’s vantage point, any potential prejudice is purportedly minimized by the brevity and content of Paragraph 4. That paragraph, the government insists, is “short,” “limited to a single sentence,” and a “single statement made in a simple and objective manner, with no elaboration or detail, much less any inflammatory matter.” *Id.* at 48-49. But, of course, if Paragraph 4 is that benign, the government will not be prejudiced in the least by having to do without it.

But the same is not true for Mr. Vepuri if the paragraph remains. In fact, the government insists on retaining Paragraph 4 precisely because of its prejudicial potential—its ability to, as the government acknowledges, “put Vepuri in a negative light” before the jury. *Id.* at 48. This is improper. *See United States v. Beedle*, 463 F.2d 721, 725 (3d Cir. 1972) (explaining that motion to strike references of the defendant’s alias should have been granted because the alias served no useful end and could only prejudice the defendant); *Georgiou*, 2009 WL 4641719, at \*7 (granting

motion to strike surplusage because its probative value was substantially outweighed by the danger of unfair prejudice); *United States v. Jasinski*, 1989 WL 156623, at \*2 (E.D. Pa. Dec. 21, 1989) (noting that the test under Fed. R. Evid. 403 and Fed. R. Crim. P. 7(d) are similar), *aff'd sub nom. Appeal of Jasinski*, 908 F.2d 962 (3d Cir. 1990), and *aff'd*, 908 F.2d 965 (3d Cir. 1990); *United States v. Desantis*, 802 F. Supp. 794, 800 (E.D.N.Y. 1992) (balancing probative value and prejudice under Rules 403 and 404(b) when considering a motion to strike surplusage); *United States v. Aosse*, 2015 WL 5050276, at \*11 (N.D. Iowa Aug. 25, 2015) (citing Fed. R. Evid. 403's advisory comment that a "statement is prejudicial if it risks 'inducing decision on a purely emotional basis'" in its analysis on a motion to strike surplusage), *aff'd sub nom. United States v. Midamar Corp.*, 2017 WL 4222857 (8th Cir. Apr. 14, 2017).

Paragraph 4 is *unfairly* prejudicial because it will unquestionably inject into the proceeding the unpleasant aroma of prior bad conduct involving Mr. Vepuri in order to suggest his propensity to act similarly in this case. *See* Fed. R. Evid. 404(b) (prohibiting evidence of any other crime, wrong, or act other than the one charged to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character). The experienced government lawyers are not oblivious to the scent, which is why they care so much about a single paragraph whose importance they try hard to downplay. On the contrary, they wish for that scent to linger and waft over the jury box—all on the basis of "relevance" claims that, for the reasons noted above, are spurious.

## **CONCLUSION**

For the foregoing reasons, and those set forth in his opening brief, Paragraph 4 of the Superseding Indictment is both irrelevant and highly prejudicial to Mr. Vepuri, and striking Paragraph 4 will visit no harm upon the government. Accordingly, Mr. Vepuri's Motion to Strike should be granted.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that, on this date, I served a copy of *Defendant Murty Vepuri's Reply in Support of His Motion to Strike Paragraph 4 of the Superseding Indictment as Irrelevant and Prejudicial Surplusage Under Federal Rule of Criminal Procedure 7(d)* upon the following via ECF and e-mail:

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